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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,316	04/26/2001	Evi Kostenis	38005-147	5658

26633 7590 08/26/2003

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/26/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/842,316

Applicant(s)
Kostenis et al.

Examiner
John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 2, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above, claim(s) 15 and 20-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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1) Claims 1 to 31 are pending in the instant application. Claims 1, 9 and 16 to 19 have been amended and claim 32 has been canceled as requested by Applicant in Paper Number 19, filed 02 June of 2003.

2) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 June of 2003 has been entered.

3) Claims 15 and 20 to 31 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 11.

4) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6) Claims 1 to 4, 8, 10 to 14 and 16 to 19 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for those reasons of record in section 5 of Paper Number 16.

Applicant has traversed this rejection on the premise that "the specification describes polypeptide

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residues containing amino acid sequence as set forth in SEQ ID NO:2 or a fragment thereof”.

The only functional protein having “EDG8” biological activity which is described in the instant specification in sufficient detail so as to permit an artisan to make it without the need to resort to undue experimentation is that single EDG8 protein comprising the amino acid sequence presented in SEQ ID NO:2. As stated in the original rejection, because the instant specification provides neither the guidance needed to predictably alter the amino acid sequence of SEQ ID NO:2 or even a single working example of a functional EDG8 protein having other than that sequence an artisan can not make a nucleic acid encoding a functional EDG8 protein having other than the amino acid sequence presented in SEQ ID NO:2 without first engaging in the undue experimentation that would be needed to identify those residues in SEQ ID NO:2 which are critical to the structural and functional integrity of an EDG8 polypeptide and those that are expendable or substitutable.

7) Claims 1 to 14 and 16 to 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite in so far as they employ the term “EDG8” as a limitation for those reasons of record as applied to claims 18 and 32 in section 11.2 of Paper Number 12. As stated therein, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of “EDG8” an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. If it is Applicant’s intention to define the limitation “EDG8 biological activity” in terms

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of a specific activity, then it is this defining activity which should be recited in the claims in place of that limitation. Applicant can not rely upon the specification to define this limitation because the specification does not provide a single unambiguous definition of the term "EDG8" or "EDG8 biological activity". If by "EDG8 biological activity" Applicant is referring to the ability to function as a S1P receptor, then the claims should refer to an "S1P receptor" instead of "a polypeptide with EDG8 biological activity".

8) Claims 1 to 14 and 16 to 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite in their recitation of the limitations "at least about 15 bases" and "at least about 10 bases". Even though the use of the term "about" in a claim is inherently vague and indefinite, its use is appropriate when employed to limit a value which is composed of infinitely divisible units such as inches, meters, grams and pints where it is impractical to produce an item which has exactly the dimension recited. Even if one could practically produce an item which is exactly 1 inch in length, the length of that item is conditional upon the temperature at which it is measured. However, when defining an invention in terms of indivisible numerical units such as the number of nucleotides in a nucleic acid, the number of amino acids in a polypeptide or the number of legs on a chair or table, the term "about" is unacceptably vague and indefinite since it is practical to employ a term which possesses the required precision. If, for example, it is Applicant's intention that the claims should encompass a nucleic acid of no less than 15 bases in length then this is exactly what the claim should recite.

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Whereas one would reasonably interpret the term "about one inch" as encompassing any value from 0.90 inches to 1.10 inches one would not know if the term "at least about 15 bases" would include or exclude 14, 13, or even 12 bases.

9) Claims 1 to 14 and 16 to 19 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by each of the Glucksmann et al. (WO 00/11166 A1, 02 Mar. 2000) and Behan et al. (WO 00/22131, 20 Apr. 2000) patent publications for those reasons of record in section 13 of Paper Number 12. As stated therein, the amino acid sequence presented in SEQ ID NO:2 of the instant application appears to be identical to the amino acid sequence presented in Figures 1A and 1B of Glucksmann et al. and amino acid residues 104 to 500 in SEQ ID NO:32 of Behan et al. Applicant's argument that the additional limitations "at least about 15 bases" and "at least about 10 bases" distinguishes the claimed polynucleotide from those that were described in these two references is incorrect because both of those references clearly meet these new limitations. For example, the nucleotide sequence presented in Figures 1A and 1B of Glucksmann et al. is 1901 bases in length.

10) Applicant's arguments filed 02 June of 2003 have been fully considered but they are not persuasive for those reasons given above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

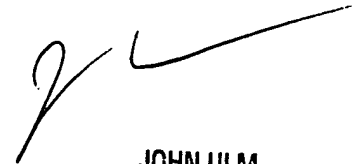
Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'JULM', with a long horizontal stroke extending to the right.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800